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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/924,110	08/07/2001	Kevin C. Carter	195/13921US03	9738

7590 09/28/2004

McAndrews, Held & Malloy, Ltd.
500 West Madison Street, #34
Chicago, IL 60661

EXAMINER

STEWART, ALVIN J

ART UNIT	PAPER NUMBER
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3738

DATE MAILED: 09/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/924,110

Applicant(s)

CARTER ET AL.

Examiner

Alvin J Stewart

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 February 2004.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,4,8,9 and 31-40 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,4,8,9 and 31-40 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 07 August 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- 1) ☐ Certified copies of the priority documents have been received.
 - 2) ☐ Certified copies of the priority documents have been received in Application No. _____.
 - 3) ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 22.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Information Disclosure Statement

The information disclosure statement (IDS) submitted on February 11, 2004 was filed. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Response to Arguments

Applicant's arguments with respect to claims 1, 2, 4, 8 and 9 have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 103

Claims 1, 2, 4, 8, 9, 31-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Campbell et al US patent 5,067,962 in view of Beck, Jr. et al US Patent 5,961,520.

Campbell et al discloses a xenograft replacement ligament comprising a bone-ligament-bone attachment with a naturally occurring attachment (see abstract and Fig. 3). The xenograft discloses a porcine or other large animals. Figure 3 discloses bone blocks shaped into a dowel. However, Campbell et al does not disclose a groove along the length of each bone block.

Beck, Jr. et al discloses an artificial ligament comprising an anchoring system made of bone (see col. 6, lines 36-39) and having a groove along the length (see Fig. 2, see element 17) for the purpose of inserting an attachment screw and attach the attachment system to the patient's bone.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the bone blocks of the Campbell et al reference with the longitudinal groove (see

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surface 17) of the Beck, Jr. et al reference in order to insert an attachment screw and attach the attachment system to the patient's bone.

Regarding claim 31, the shape of the Beck, Jr. et al reference can be used bi-directionally.

Regarding claim 32, it is an inherent characteristic of the process of preparing the xenograft material in order to be inserted in a human joint.

Regarding claim 33, see holes 25 & 26.

Regarding claim 34 & 37, at the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to modify the shape of the Campbell et al reference by having a cylindrical shape or square cross section because Applicant has not disclosed that the cylindrical shape provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with taper shape of the Campbell et al reference because it will perform equally the same.

Therefore, it would have been an obvious matter of design choice to modify Campbell et al reference to obtain the invention as specified in claim 34.

Regarding claim 35, Campbell et al disclose the claimed invention except for a cylindrical dowel diameter of 9 through 12mm. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the diameter of the Campbell et al reference with the optimum value of 9 through 12mm, since it has been held that finding an optimum value of a result effective variable involves only routine skill in the art. In re Boesch, 617 F. 2d 272, 205 USPQ 215 (CCPA 1980).

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Regarding claims 38-40, at the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to modify the Campbell et al reference with a first naturally occurring bone derived from a patella and a second naturally occurring bone derived from a tibia because Applicant has not disclosed that a first bone block derived from the patella and a second bone block derived from a tibia provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with a donor animal ligament that is capable of having the size and strength of the patients injured ligament because it will be capable of withstanding the forces exerted in the patients knee joint.

Therefore, it would have been an obvious matter of design choice to modify the Campbell et al reference to obtain the invention as specified in claim 38.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

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however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alvin J Stewart whose telephone number is 703-305-0277. The examiner can normally be reached on Monday-Friday 7:00AM-5:30PM(1 Friday B-week off).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on 703-308-2111. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Alvin J Stewart
Primary Examiner
Art Unit 3738

September 22, 2004.